

CERHR NOMINATION AND SELECTION PROCESS

Lead Discussants

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Discussion Question

What role would the BSC like to assume in the selection of chemicals for CERHR expert panel evaluations (see below “POTENTIAL ROLE FOR BSC IN THE SELECTION PROCESS”).

BACKGROUND ON CERHR

NIEHS established the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) in June 1998. The CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with environmental and occupational exposures. Expert panels conduct scientific evaluations of agents selected by the CERHR in public forums.

The CERHR invites the nominations of environmental agents for review by expert panels and of scientists for its expert registry. Information about CERHR and the nomination process can be obtained from its homepage (<http://cerhr.niehs.nih.gov>) or by contacting the center directly (919-541-3455). The CERHR selects chemicals for evaluation based upon several factors including production volume, potential for human exposure from use and occurrence in the environment, extent of public concern, and amount of data available from reproductive and developmental toxicity studies.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process is available on the CERHR website under "About CERHR" or in printed copy from the CERHR.

CHEMICAL NOMINATION AND SELECTION PROCESS

CERHR invites the nomination of substances for expert panel evaluation from any individual or organization. Nominations should contain a rationale or reason for the proposed evaluation and, if possible, appropriate background information and relevant data (*e.g.*, personal concern, journal articles, exposure information, etc.) to support the rationale.

The multi-agency CERHR Core Committee considers each nominated substance to determine whether the available scientific information justifies a formal evaluation. Typically, preliminary dossiers are prepared on the substances nominated soon after nominations are received and the Core Committee, at its next quarterly meeting, reviews these dossiers and determines the extent of available information and interest. At this point the Core Committee may ask that a full dossier be prepared for review at its

subsequent meeting, may defer a decision if interest is high but information is lacking, or may “not select” the substance if there is insufficient information and interest. Full dossiers are reviewed and substances are recommended for possible expert panel evaluation. The Core Committee bases its recommendations for evaluation on a substance’s production volume, potential human exposure, amount of available scientific information about a substance’s reproductive and developmental toxicity, and degree of public concern. A nomination might not be selected for evaluation for several reasons, including (1) insufficient scientific information to evaluate whether the substance is a reproductive or developmental toxicant, (2) existence of a recent evaluation of reproductive and development risks conducted by another agency or organization, (3) absent or limited information on human exposures, or (4) insufficient public health concern.

The CERHR announces the substances selected for expert panel evaluation and solicits public comments on them through announcements in the Federal Register and NTP publications. These announcements also invite the submission of new data and information about planned or ongoing studies, exposure, and patterns of use. In addition, CERHR invites the public to identify scientists qualified to serve on an expert panel for each specific evaluation. The CERHR considers this input to select and prioritize candidate substances for evaluation.

EXAMPLES OF NOMINATIONS AND DECISIONS

To help familiarize the BSC with the current selection process, two examples of nominated chemicals, the information considered, and the decisions reached are presented here.

Bisphenol A (BPA) was the substance most recently selected for CERHR expert panel evaluation. BPA is used to make numerous consumer products including polycarbonate food and drink containers. BPA was nominated for evaluation in 2001 and was deferred by the Core Committee. It was considered again in 2003 and again deferred. Based on widespread human exposure, growing databases on reproductive and developmental effects, and increasing public concern, BPA was selected for expert evaluation in 2005. At that time there were 65 publications on developmental toxicity in animals, 37 publications on reproductive toxicity in animals, and 43 publications on BPA exposure. Exposure publications reported BPA levels in food, materials, and the environment, and exposure levels in the general population, occupational groups, and in maternal/fetal pairs. Three scientists outside NIEHS reviewed the documents supporting the selection of BPA. All agreed that it warranted expert panel evaluation.

Lead (Pb) was first nominated to CERHR in 1999 and three more nominations were received in 2000. A decision on Pb was deferred because of wide recognition that it is a human reproductive toxicant and developmental neurotoxicant. A scientist at NIOSH nominated Pb again in 2006. The rationale for this nomination was as follows. Current occupational exposure limits allow workers, including pregnant women, to have blood lead levels of 40µg/dL. Some guidelines state that blood lead levels of 10-19 µg/dL are

associated with possible spontaneous abortion and reduced newborn birth weight, and that possible adverse population effects are suggested by epidemiologic studies at levels below 10µg/dL. A thorough scientific evaluation of possible reproductive and developmental effects at low lead levels would aid NIOSH as it considers revising its recommended exposure limit for lead. A full dossier on lead will be considered by the CERHR Core Committee at its meeting on January 26, 2007. The major issue to be considered is the extent of the available database addressing reproductive and developmental effects at exposure levels resulting in blood lead levels at 40µg/dL and lower.

POTENTIAL ROLE FOR BSC IN THE SELECTION PROCESS

The NTP would like for the NTP Board of Scientific Counselors (BSC) to consider playing an advisory role in the selection of chemicals for CERHR expert panel evaluations and provide its thoughts on this issue at the upcoming meeting.

Specifically, chemicals recommended for expert panel evaluation by the CERHR Core Committee would be brought before the NTP BSC for discussion. BSC members would be assigned to serve as lead discussants on each chemical; in some instances, the NTP might include *ad hoc* members to assist with a review. Dossiers would be provided in the meeting materials and, when available, public comments submitted prior to the meeting would be provided; the public would also be invited to present oral comments at the meeting. At the meeting, CERHR would present the reasons for a chemical's recommendation for expert panel evaluation. Following the presentation and public comments (if any), the NTP would ask the BSC whether it feels there is sufficient concern and scientific data to warrant expert panel evaluation of the chemical. In reaching a decision, the NTP would ask the BSC to consider the following factors:

- Production volume
- Potential human exposure
- Amount of published scientific information about the substance's reproductive and developmental toxicities
- Extent of public concern